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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,577

02/23/2004

Lung-Ji Chang

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03/17/2008

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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/785,577	<b>Applicant(s)</b> CHANG, LUNG-JI	
	<b>Examiner</b> Anne-Marie Falk, Ph.D.	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 29-50 is/are pending in the application.
- 4a) Of the above claim(s) 29-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The amendment filed December 14, 2007 (hereinafter referred to as “the response”) has been entered. Claim 17 has been amended.

The elected invention is drawn to a tumor cell composition comprising a tumor cell modified to express a B7-2 protein and at least one additional immune modulator, or a functional fragment of said B7-2 protein or said immune modulator. Applicants further elected GM-CSF as the cytokine species for prosecution.

Claims 17-20 and 29-50 are pending in the instant application.

Claims 29-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the replies filed on February 28, 2007 and July 12, 2007.

Accordingly, Claims 17-20 are examined herein.

The rejection of Claims 17-20, under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is withdrawn in view of the amendment to Claim 17 to remove reference to functional fragments.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-20 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,548,068 (Schlom et al., priority to 6/7/95).

The claims are directed to a tumor cell composition consisting essentially of a tumor cell modified to express a B7-2 protein and at least one additional immune modulator. Dependent claims further specify that the immune modulator is a cytokine and that the cytokine is GM-CSF.

Schlom et al. disclose and claim a tumor cell modified to express B7-2 and GM-CSF. See especially Claims 1, 4, and 5. Claim 1 is directed to a host cell infected with a recombinant vaccinia virus which has incorporated into the viral genome a gene or portion thereof encoding B7-2. The claim further specifies that the B7-2 gene is expressed. Claim 4 is directed to the host cell according to Claim 1 wherein the recombinant virus further comprises one or more genes or portion thereof encoding an immunostimulatory molecule selected from the group consisting of IL-2, ICAM-1, LFA-3, CD72, GM-CSF, TNF $\alpha$ , INF $\gamma$ , IL-12, IL-6 and combinations thereof. Claim 5 is directed to the host cell according to any one of Claims 1 to 4 “wherein the host cell is ...a tumor cell ...” Thus, the patent clearly discloses a tumor cell modified to express both B7-2 and GM-CSF, as instantly claimed.

Thus, the claimed invention is disclosed in the prior art.

At pages 5-6 of the response, Applicants assert that Schlom discloses recombinant viruses and host cells infected with the recombinant viruses wherein the virus, or the host cell, express at least a tumor associated antigen and an immunostimulatory molecule. Applicants allege that Schlom does not disclose a tumor cell composition consisting essentially of a tumor cell modified to express B7.2 and at least one additional immune modulator because the compositions disclosed by Schlom all require expression of a tumor associated antigen. Applicants are reminded that the term “tumor cell,” as recited in the instant claims, includes everything that may be expressed in or on a tumor cell and therefore does not exclude

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natural tumor cell components, such as a tumor-associated antigen. Accordingly, the instant claims read on the tumor cell compositions disclosed in the prior art.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis original). For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See MPEP 2111.03.

At page 6, paragraph 3 of the response, Applicants allege that Schlom does not disclose each and every element of the pending claims. On the contrary, Schlom et al. disclose a tumor cell modified to express both B7-2 and GM-CSF, as instantly claimed. Nothing more is required.

### ***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/  
Primary Examiner, Art Unit 1632